Formulary Criteria: Quadrivalent Human Papillomavirus (Types 6/11/16/18) Recombinant Vaccine (Gardasil®)

VHA Pharmacy Benefits Management Strategic Healthcare Group and the Medical Advisory Panel

The following recommendations are based on current medical evidence. The content of the document is dynamic and will be revised as new clinical data become available. The purpose of this document is to assist practitioners in clinical decision making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. The clinician, however, must make the ultimate judgment regarding the propriety of any course of treatment in light of individual patient situations.

The quadrivalent vaccine has been approved to prevent disease associated with HPV types 6/11/16/18 in girls and women aged 9-26 years. The vaccine is not a therapeutic vaccine and will not prevent disease associated with HPV vaccine types in which a girl or woman has been or is currently infected but will be effective for prevention of disease caused by the remaining HPV vaccine types with which they have not been previously infected. (For details refer to the monograph at http://vaww.pbm.va.gov or www.pbm.va.gov)

EXCLUSION CRITERIA (If one is selected, patient is not eligible)

- Female >26 years of age
- Male
- Pregnancy
- Individuals with a history of immediate hypersensitivity to yeast or other components of the vaccine

INCLUSION CRITERIA

- Female 9-26 years of age

Dosage, Administration and Storage

- Gardasil® is administered intramuscularly as 3 separate 0.5 ml doses. The first dose is followed by 2 additional doses given at 2 and 6 months after the initial dose.
- The vaccine should be shaken well immediately before use. No reconstitution or dilution is necessary. The vaccine should be given intramuscularly in the deltoid region of the upper arm or in the higher anterolateral area of the thigh.
- The vaccine should be refrigerated (2-8ºC, 36-46ºF). It should be protected from light and should not be frozen.
- (Contents of vaccine: 20 mcg HPV 6 L1 protein/40 mcg HPV 11 L1 protein/40 mcg HPV 16 L1 protein/20 mcg HPV 18 L1 protein. Also 225 mg aluminum (as amorphous aluminum sulfate adjuvant), 9.56 mg NACL, 0.78 mg L-histidine, 50 mcg polysorbate 80, 35 mcg sodium borate and water for injection. The product does NOT contain preservatives).

Issues For Consideration

- The American Cancer Society has released their recommendations for the HPV vaccine. They recommend offering the vaccine to those women aged 19-26 years while taking into consideration their number of lifetime sexual partners. (The risk of prior acquisition of HPV increases with increasing number of lifetime sexual partners potentially rendering the vaccine less effective).[1]
- The importance of continued routine cervical cancer screening with Pap smear tests should be reinforced in both vaccinated and unvaccinated women.
- The American College of Obstetricians and Gynecologists (ACOG) and the American Cancer Society (ACS) do NOT recommend testing for HPV infection prior to vaccination (Testing only indicates current but not past infection).
- Click on this link for patient information related to the quadrivalent HPV vaccine http://www.cdc.gov/nip/publications/VIS/vis-hpv.pdf

References

1. American Cancer Society Guideline for Human Papillomavirus (HPV) Vaccine use to Prevent Cervical Cancer and its Precursors. CA Cancer J Clin 2007;57:7-28.
2. http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5602a1.htm (Final recommendations from the ACIP. Accessed 4-3-07).

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Updated versions may be found at www.pbm.va.gov or http://vaww.pbm.va.gov